

REMARKS/ARGUMENT

Description of amendments

Claims 1-15 and 18-26 are pending after entry of this Amendment, of which Claims 2, 3, 10, 12, 15, 18 and 26 are withdrawn as subject to a restriction requirement. No new matter is introduced by this Amendment.

The Office's Answer to Applicants' previous traverse

The undersigned appreciates the Examiner's efforts in explaining why the Office believes the Applicant's prior traverse was not persuasive.

In Applicants' prior traverse, it was stressed that the claims are reciting structure that is nowhere found in any art, nor obvious over a combination of art. In response, the case of *In re Masham* is cited repeatedly to reject the claims. A copy of this case is enclosed for the Examiner's consideration.

In re Masham deals with the situation where an applicant's claims recite an apparatus for performing a process where the only distinction between a prior art process's inherent features and the claim is the product, contents or result of the process when being used in the manner intended by the patent applicant. The claim in *In re Masham* was directed to "An apparatus for mixing flower developer material. . .". This "apparatus" was known, as was its capability for "mixing" as required to meet applicants' intended purpose. The only teaching that was missing from the prior art reference was its use for mixing flower developer material. However, because the prior art reference's disclosed process could inherently perform the task required for mixing flower developer material, the applicant's claims were not patentable because the only difference was the contents or product that resulted from the intended use. In addition, the prior art in *Masham* also did not need modification so that it could become capable of performing the intended use.

There is an important difference between the present case and the one faced by the board in *Masham*. In this case, the prior art apparatus must be modified so that it becomes capable of performing Applicants' intended use. No modification of the prior art was necessary to perform the intended use in *Masham*. Thus, the appropriateness of the rejection depends at least upon

whether one of ordinary skill in the art would have considered it obvious to modify *Hattler*'s multi-lumen catheter as suggested if faced with the same or a different problem as that faced by the Applicants at the time of invention. As such, ***In re Masham is irrelevant to the patentability of Applicants' claims unless the Office can first meet the threshold showing of a prima facie case of obviousness.***

Rejections under 35 U.S.C. §103(a)

Claims 1, 4-8 are rejected under 35 U.S.C. 103(a) as obvious over US4846791 ("*Hattler*") in view of US5674208 ("*Berg*"). Claims 1, 4-8 are also rejected under 35 U.S.C. 103(a) as obvious over US4846791 ("*Hattler*") in view of US5389106 ("*Tower*"). Claims 9, 11, 13-14 and 19-25 are rejected under 35 U.S.C. § 103(a) over *Hattler*, US4762128 ("*Rosenbluth*") and "Applicant's Admitted Prior Art". See Page 6 of the Official Action.

As Applicants understand, each of the above rejections are based, at least in part, on the following conclusion: it would have been obvious to replace the catheter tube in *Hattler* with a stent. **Applicants traverse the rejections based on *Hattler* and *Berg*, *Hattler* and *Tower*, and *Hattler*, *Rosenbluth* and the so-called admitted prior art because each of these modifications would have rendered *Hattler* unsuitable for its intended purpose.**

Hattler's multi-lumen catheter is used to deliver therapeutic substance to the body intravenously. This catheter is intended to address the need for a multi-lumen intravenous catheter which can be delivered through tortuous vessels. The solution is to first place the catheter in the body and then insert a "divider" structure into the catheter so as to configure the catheter with multiple fluid-tight lumens for delivery of different medications. *See* Col. 2. In order to meet this need, *Hattler* considers it mandatory that the divider and/or catheter adhere to the following : (1) the catheter's walls are fluid impermeable, col. 1, ll. 10-24; col. 4, ll. 51-55; (2) the catheter is flexible enough to pass through tortuous arteries, col. 4, ll. 27-29; col. 5, ll. 18-22; and (3) the divider must be capable of forming a fluid tight seal with the walls of the catheter, col. 4, ll. 51-55.

According to the Official Action, it would have been obvious to replace *Hattler*'s catheter tube with any known stent or catheter. *See* page 3. Further, it would have been obvious to replace

Hattler's catheter tube with a stent having “a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts.”. *See* page 7. Finally, it would have been obvious to configure a divider in this stent such that the divider did not touch the walls of the catheter. *See* page 4.

In deciding obviousness cases, “[i]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)”. MPEP § 2143.01

(1) Applicants' claims are not obvious because *Hattler's* catheter's walls must be fluid impermeable.

If the walls of *Hattler's* tube are not fluid impermeable, then he does not have a multi-lumen catheter. Thus, even if it would have been obvious to replace the tube 10 with a tube having an embedded stent structure, this tube could not be a stent with “a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts” because it would render the resulting device unsuitable for *Hattler's* intended purpose, i.e., providing a multi-lumen catheter with fluid tight seals. As such, Applicants' Claims 1, 9, 19, 20, 23 and 24 would not have been obvious in view of the prior art. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)”. MPEP § 2143.01.

(2) Applicants' claims are not obvious because *Hattler's* catheter must be flexible enough to pass through tortuous arteries

Hattler's tube 10 must be flexible enough so that it can navigate through tortuous tissue. If this tube were replaced with a stent, then the tube could no longer perform this function. Stents are significantly higher in flexural rigidity than catheter tubes, because they are used for such purposes as a scaffolding or as a graft. It certainly cannot be disputed that if the catheter tube were replaced by a stent it would not be able to follow the natural curvature of a blood vessel without causing damage because a stent lacks this kind of flexibility. Moreover, Applicants have never heard of a stent that would have the length required for *Hattler's* apparatus. Accordingly, the suggested modification of replacing the catheter tube 10 with a stent would have rendered the

device unsuitable for *Hattler*'s intended purpose. As such, Applicants' Claims 1, 9, 19, 20, 23 and 24 would not have been obvious in view of the prior art. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)". MPEP § 2143.01

(3) Applicants' Claim 6 is also not Obvious because the prior art does not teach all limitations, and/or because *Hattler*'s divider must be capable of forming a fluid tight seal with the walls of the catheter

Applicants' Claim 6 recites wherein the plurality of spikes do not contact the luminal surface of the stent. In addition to the reasons given above, Claim 6 is not obvious over the prior art for the following reasons.

Nowhere does *Hattler* suggest that the divider need not contact the walls of the tube 10. If this were true, the statement would flatly contradict everything that is set forth in the background and summary of invention. Contrary to the suggestion in the Official Action, *Hattler* requires that a fluid tight seal is formed when the divider is inserted into the tube. Therefore, it is not possible that *Hattler* would teach a divider that does not contact walls of the tube. Thus, the combined art fails to teach every feature of Claim 6. Furthermore, if *Hattler*'s divider were replaced with one that did not create a fluid-tight seal (i.e., one that did not touch the walls of tube 10), then the resulting device would, once again, be unsuitable for *Hattler*'s intended purpose. For either of these reasons, Claim 6 would not have been obvious over the prior art.

For the above reasons, Applicants respectfully ask that all pending rejections under 35 U.S.C. § 103(a) be withdrawn. Allowance of Claims 1, 9, 19, 20, 23, and 24 is earnestly solicited.

Claims 4-8, 11, 13, 14, 21, 22 and 25 depend from Claims 1, 9, 19, 20, 23, and 24 and recite additional features that further distinguish Applicants' invention over the art of record. However, it is not necessary to point out the additional features recited in these dependant claims. Because Claims 4-8, 11, 13, 14, 21, 22 and 25 depend from allowable claims, they are also not obvious over the art of record.

Withdrawal of the rejections to Claims 4-8, 11, 13, 14, 21, 22 and 25 and allowance of these claims is earnestly solicited.

Application No. 10/750,312
Amendment dated February 12, 2008
Reply to Office action of 12/12/2007

Withdrawn Claims 2, 3, 10 and 12

Claims 2, 3, 10 and 12 are subject to a species-type restriction requirement. As these claims now depend from allowable parent claims, withdrawal of the restriction requirement and allowance of Claims 2, 3, 10 and 12 is also requested.

Conclusion

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

Date: Feb. 12, 2008

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